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(21) International Application Number: PCT/EP98/05900 (22) International Filing Date: 17 September 1998 (17.09.98) (30) Priority Data: 9719775.0 18 September 1997 (18.09.97) GB (71) Applicant (for all designated States except US): GLAXO GROUP LIMITED [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): ANDERSON, Gregor, John, McLennan [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts SG12 0DP (GB). ROBERTSON, Duncan [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts SG12 0DP (GB). (74) Agent: FILLER, Wendy, A.; Glaxo Wellcome plc, Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: INTRANASAL ADMINISTRATION DEVICE (57) Abstract <p>The present invention relates to a device for the intranasal administration of powdered medicaments. Specifically, the device comprises a cavity where the medicament to be dispensed is placed. As the patient inhales, air is drawn into the cavity through at least two air inlet slots. The arrangement of the air inlet slots cause the air to rotate within the cavity. The swirling motion of the air disperses the medicament within the cavity and picks up the powder. The required amount of powder is drawn up an outlet nozzle in a rotating column of air and out through a nasal adapter.</p> <div data-bbox="609 1113 1339 1606" data-label="Image"> </div>		

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INTRANASAL ADMINISTRATION DEVICE

The present invention relates to devices by which powdered medicaments may be intranasally administered.

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Devices adapted for the intranasal administration of powdered medicaments are known. However, such devices are only suitable for administering small amounts of powdered medicaments.

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According to the present invention, there is provided a device specifically adapted for the intranasal administration of powdered medicaments. The device comprises a body portion which is preferably in two parts, a cavity in which the substance to be administered is deposited, at least two air inlet slots in communication with the cavity, an outlet nozzle communicating with the cavity and a nasal adapter which in operation communicates between the patient's

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nostril and the outlet nozzle.

The air inlet slots which are in communication with the cavity are adapted so that air flowing through them into the cavity is caused to rotate within the cavity. The swirling motion of the air effects the dispersal of the medicament within the cavity and ensures that the required amount of the medicament is efficiently expelled from the cavity and out through the outlet nozzle. The air inlet slots may radiate outwards from the cavity at an angle which is upwardly inclined in relation to the plane of the cavity. Preferably, the air inlet slots are in tangential communication with the cavity. In a particularly preferred embodiment, the air inlet slots are in tangential communication with the cavity and radiate outwards from the cavity at an angle which is upwardly inclined in relation to the plane of the cavity.

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For effective dispersal of the medicament within the cavity and efficient discharge of the medicament from the cavity the device will possess at least two air inlet slots. Preferably the device will comprise three air inlet slots.

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During the intranasal administration of powdered medicaments it is important that an effective seal is formed between the nose of the patient and the nasal

adapter through which the substance flows. If an inefficient seal is formed, as the patient inhales through his nose air will leak in around the seal and an insufficient dose of the medicament may be discharged from the device. The nasal adapter of the present device is specifically adapted to ensure that in substantially all of the patients using the device an effective seal is formed between the nasal adapter and the patient's nose, thereby ensuring efficient operation of the device. The nasal adapter will be suitably shaped to provide a snug fit with the patient's nostril. Preferably, the nasal adapter will be a hollow tapering member projecting from the body portion of the device such that as the member projects away from the body portion of the device the exterior diameter of the adapter decreases.

The medicament to be administered by the device flows from the cavity to the nasal adapter *via* the outlet nozzle. By judicious choice of dimensions, the outlet nozzle may be adapted to ensure that the medicament is administered to the patient at an effective rate.

The device may be fabricated from any suitable material. Suitable materials include plastics, card, paper and metals. Preferred materials comprise thermoplastic elastomers. A particularly preferred material is acrylonitrile-butadiene-styrene.

Preferably, the body portion of the device is composed of two parts; one part, conventionally called the cover member, partly enclosing the other part, conventionally called the base. The cover member includes the outlet nozzle which communicates with the cavity. The base includes the cavity and the air inlet slots. Preferably, the cover member may be removably attached to the base, such attachment may be accomplished by any suitable means for example by gripping engagement, snap fit connection or screw thread engagement. However, the cover member may be in hinged engagement with the base portion of the device, pivotal movement about the hinge allowing access to the cavity. When the two parts of the device are in engagement, there is an opening between the cover member and the base to allow air to flow through into the air inlet slots and on into the cavity.

Incorporation of a detachable cover member allows the device to be refilled and thereby used more than once. The device may also be presented in a form suitably adapted for the administration of only one single dose. Moreover, the device may be adapted for the administration of a plurality of doses, for example
5 by providing a reservoir of the medicament which can be metered out into the required unit dose quantities.

For operation, the medicament to be dispensed is placed within the cavity. As the patient inhales, air is drawn in to the cavity through the air inlet slots. The
10 arrangement of the air inlet slots cause the air to rotate within the cavity. The swirling motion of the air disperses the medicament within the cavity and picks up the powder. Optionally the device may incorporate baffles to ensure efficient dispersal of the medicament. The required amount of powder is drawn up the outlet nozzle in a rotating column of air and out through the nasal adapter and
15 enters the patient's nose.

Although the device according to the invention has thus far been described for use in intranasal administration of medicaments, it is also suitable for the administration of medicaments by inhalation. The necessary adaptation for this
20 mode of administration will be readily apparent to those skilled in the art and may take the form of a mouthpiece rather than a nasal adapter.

The device is adapted to deliver up to 20 mg of powder, suitably up to 15 mg of powder, preferably up to 10 mg of powder.
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A preferred embodiment of the invention is described in detail below, by example only, with reference to the accompanying drawings, wherein:

Figure 1 is a section view through the complete dispensing device;
30 Figure 2 is a plan view of the cover member from below;
Figure 3 is a section view through the cover member;
Figure 4 is a perspective view of the cover member from above;
Figure 5 is a perspective view of the cover member from below;
Figure 6 is a section view through the base of the device;
35 Figure 7 is a perspective view of the base from above; and

Figure 8 is a plan view of the base of the device.

As illustrated in Figure 1 the device comprises two portions, the cover member (1) and the base (2). In operation the medicament to be dispensed is placed in the cavity (3), the nasal adapter (4) is sealed against the nostril of the patient and the patient inhales, thereby air is drawn in through the small space (5) between the cover member (1) and the base (2). The air flows into the cavity (3) via the air inlet slots (6) which by their arrangement cause the air to rotate within the cavity (3). The swirling motion of the air disperses the medicament within the cavity (3) and picks up the powder. The powder is drawn up the outlet nozzle (7) in a rotating column of air and out through the nasal adapter (4).

Figures 2, 3, 4 and 5 illustrate the cover member (1) of the device, which comprises the outlet nozzle (7). The outlet nozzle (7) is formed by a cylindrical aperture which extends all the way through the cover member (1). The outlet nozzle (7) protrudes from the cover member at one end to form the nasal adapter (4) and protrudes from the cover member at the other end to engage with the cavity (3). The circumference of the cover member is raised to form a rim (8) which engages on the base of the device. The nasal adapter (4) is a hollow tapering member projecting from the cover member (1) of the device such that as the member projects away from the body portion of the device the exterior diameter of the nasal adapter (4) decreases.

Figures 6, 7 and 8 illustrate the base of the device (2) which comprises the cavity (3) in which the substance to be administered is deposited and the air inlet slots (6a, 6b, 6c). The three the air inlet slots (6a, 6b, 6c) are equally spaced around the cavity and are in tangential communication with the cavity radiating outwards from the cavity at an upwardly inclined angle in relation to the plane of the cavity.

Claims

- 5 1. A device specifically adapted for the intranasal administration of powdered medicaments. The device comprises a body portion, a cavity in which the substance to be administered is deposited, at least two air inlet slots in communication with the cavity, an outlet nozzle communicating with the cavity and a nasal adapter which in operation communicates between the patient's nostril and the outlet nozzle.
- 10 2. A device according to claim 1 wherein the air inlet slots are in tangential communication with the cavity and radiate outwards from the cavity at an angle which is upwardly inclined in relation to the plane of the cavity.
- 15 3. A device according to claim 1 or claim 2 wherein the nasal adapter is a hollow tapering member projecting from the body portion of the device such that as the member projects away from the body portion of the device the exterior diameter of the adapter decreases.
- 20 4. A device according to any of claims 1 to 3 wherein the body portion is composed of two parts; one part partly enclosing the other part.
5. A device according to claim 4 wherein the cover member partly encloses the base.
- 25 6. A device according to claim 4 or claim 5 wherein when the two parts of the device are in engagement, there is an opening between the cover member and the base to allow air to flow through into the air inlet slots and on into the cavity.
- 30 7. A device according to any of claims 4 to 6 wherein the cover member is removably attached to the base.
8. A device according to claim 7 wherein the cover member includes the outlet nozzle which communicates with the cavity.

9. A device according to claim 7 wherein the base includes the cavity and the air inlet slots.
- 5 10. A device according to claim 9 which is adapted to deliver up to 10 mg of powder.

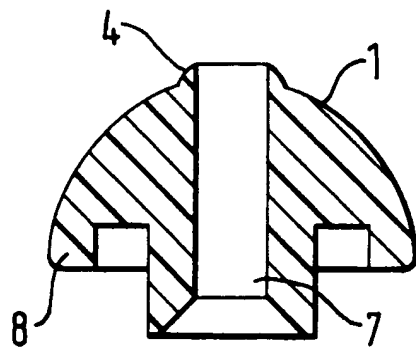
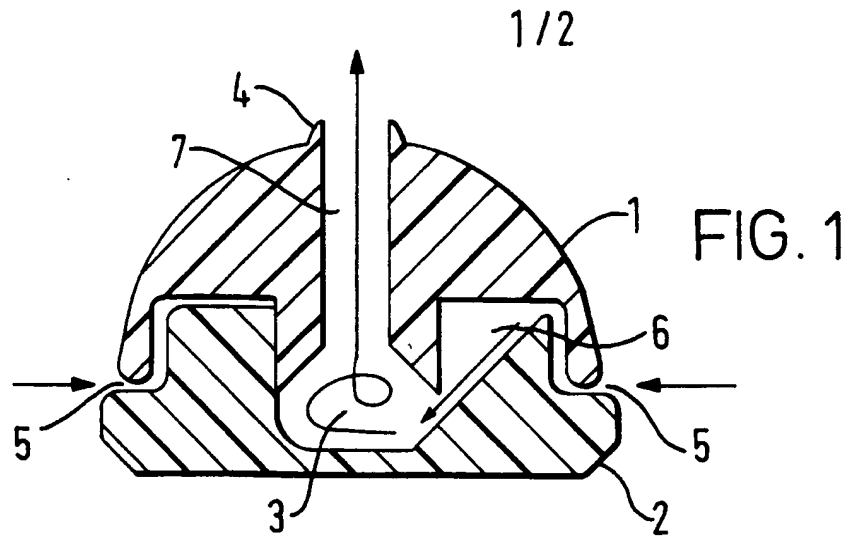


FIG. 3

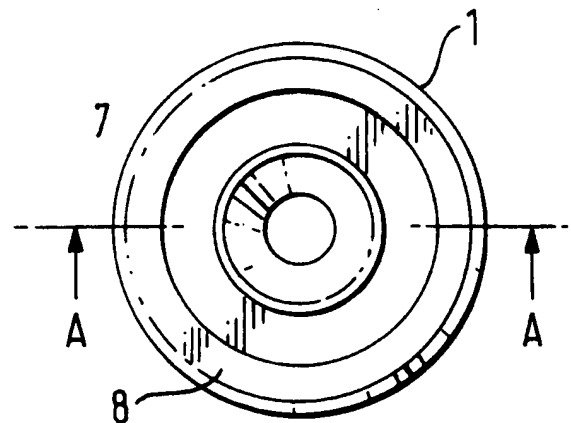


FIG. 2

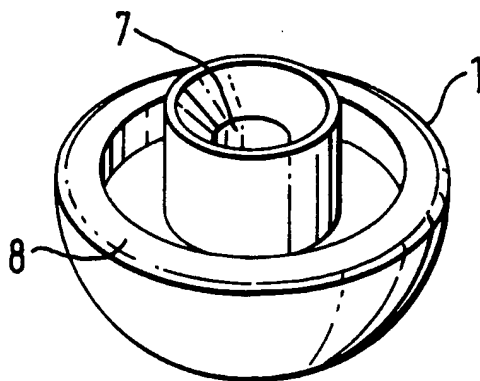


FIG. 5

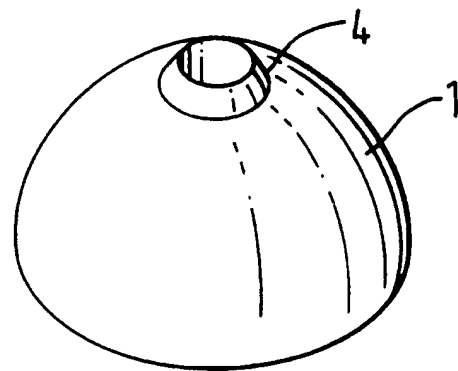


FIG. 4

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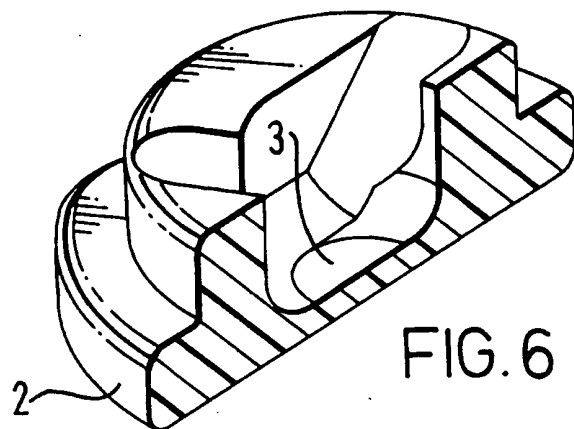


FIG. 6

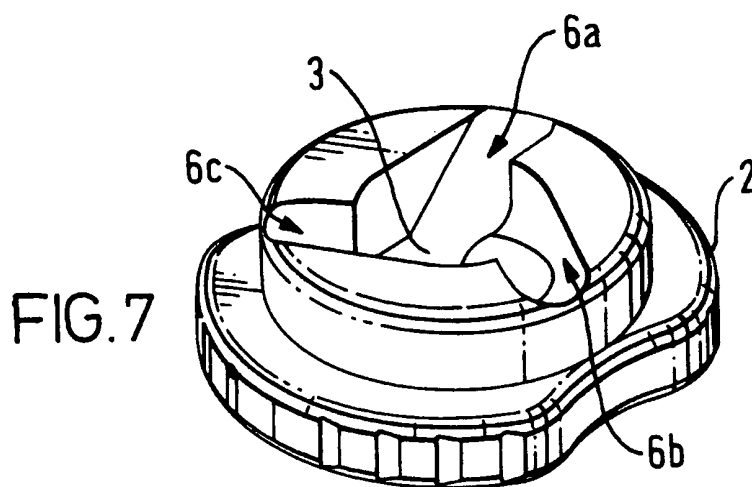


FIG. 7

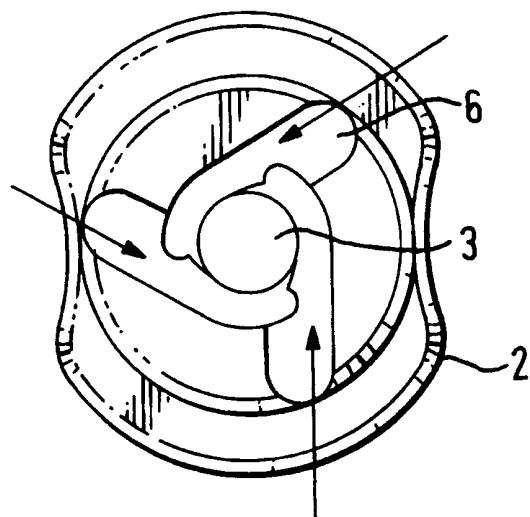


FIG. 8

International Application No
PCT/EP 98/05900

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 878 106 A (ARMOUR) 27 September 1961 see page 1, column 1, line 1 - line 31 see page 2, column 2, line 74 - line 119 see page 3, column 1, line 11 - line 37 see claim 4 see figure 3 ---	1-4,6-10
X	US 2 579 280 A (TRUMBOUR) 18 December 1951 see column 1, line 51 - column 2, line 30 see column 3, line 10 - line 28 see figure 1 ---	1-4,6-9
X	US 2 604 094 A (MILLER) 22 July 1952 see column 2, line 3 - line 49 see figures 1-4 ---	1,3,4, 6-9

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NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

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X	US 2 672 865 A (HARRY) 23 March 1954 see figures 2,4 see column 2, line 1 - line 52 -----	1-5,7,8
A	EP 0 696 458 A (ATSUGI UNISIA CORP ;DOTT LTD COMP (JP)) 14 February 1996 see figures 1,8,10 see column 6, line 20 - line 35 see column 8, line 1 - line 10 see claim 1 -----	1,5

INTERNATIONAL SEARCH REPORT

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 878106 A		FR 1220378 A	24-05-1960
US 2579280 A	18-12-1951	NONE	
US 2604094 A	22-07-1952	NONE	
US 2672865 A	23-03-1954	GB 705404 A	
EP 0696458 A	14-02-1996	JP 8047531 A	20-02-1996
		CN 1118698 A	20-03-1996
		DE 696458 T	10-10-1996
		US 5619985 A	15-04-1997

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